# FibroScan® 502 TOUCH

# User Manual

CE
0459

E300M017.4 – Version 4 – 03/2017

(software version C 3.1)

en-US

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# 1. PURPOSE OF THE USER MANUAL

This User Manual has no contractual value whatsoever and under no circumstances may Echosens be held responsible on the basis of the information contained in this Manual.

This User Manual details, on the one hand, all of the information required for the implementation, use and maintenance of the FibroScan device and, on the other hand, the list of information displayed.

Thus, after carefully reading the manual, operators will be able to:

- connect peripheral elements (power cable, USB devices, probes) and power up the FibroScan device,
- configure the device,
- navigate the device's user interface,
- perform basic maintenance.

Echosens publishes this manual "as is", without guarantees of any nature, whether explicit or implicit, including, but not limited to implicit guarantees or merchant conditions, or adaptation for specific use in view of providing simple and accurate information. Consequently, Echosens SA cannot accept any responsibility for any incorrect interpretation of the Manual. Although all efforts have been made to offer a manual that is as accurate as possible, this manual may nevertheless contain some technical inaccuracies and/or typographical errors.

Echosens cannot, under any circumstances, be held responsible for any loss of profit, loss of business, data loss, business interruption, or for any indirect, specific, accidental or consecutive damages of any type. In the event of damages arising from a defect (imperfection) or error contained in this User Manual, Echosens undertakes to send the physician, as rapidly as possible, a hard copy or electronic document containing all corrections made to this manual.

This manual is updated on a regular basis. The most recent version of this manual is available from Echosens on request. Should any major modifications be made to the manual, however, Echosens undertakes to send the physician, as rapidly as possible, a new copy of the manual in hard copy or electronic format. Note that this does not involve updating the hardware and/or software in your possession.

The product owner must keep this manual for as long as the product is used.

This manual contains a chapter for troubleshooting the most commonly encountered problems.

Any information or modification requests pertaining to this manual should be sent to: Echosens, 30 place d'Italie, 75013 Paris, France.


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## 1.1. SYMBOLS USED IN THE MANUAL

This symbol means: CAUTION

Warning: See the instructions before using the medical device.

Instructions preceded by this symbol may cause injuries or damage the medical device and installation if not correctly followed.

This symbol means: INFORMATION

Additional information with no impact on device use.

## 1.2. PROPERTY AND COPYRIGHT

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# 2. WARNINGS

## 2.1. GENERAL INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician.

## 2.2. ELECTRICAL SAFETY

To avoid the risk of electric shock, this device must be connected to an grounded power supply only.

Multi-socket adapters and extension leads must not be connected to the device.

The power cable socket is intended for use as an isolating device and must be easily accessible to prevent connection problems.

All peripherals connected to signals input/output must be certified according to standard IEC 60950-1.

Any parts not specified in the User Manual must not be connected to the system.

Correct grounding operation can only be guaranteed if the system is connected to a socket compliant with safety standards.

Make sure that the vents are not obstructed. If they are, the electronic equipment may overheat, causing irreversible damage.

## 2.3. ELECTROMAGNETIC SAFETY

The use of accessories not specified in the User Manual may cause a non-compliance in terms of electromagnetic compatibility (EMC).

Avoid using the FibroScan device when placed upon or near a machine that generates electromagnetic disturbance.


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The FibroScan 502 TOUCH device requires special precautions to be taken concerning electromagnetic compatibility (EMC). It must be installed and set up according to the EMC information given in this manual.

## 2.4. USING THE DEVICE

Do not push or lean on the top of the FibroScan device.

To avoid tipping the FibroScan when moving it, move it slowly sideways and steer it firmly by holding the decorative rods on the front and back of the device.

To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.

## 2.5. DELETING MEASUREMENTS

All measurements taken before the one chosen for deletion will be eliminated from the examination after confirmation.

## 2.6. SWITCHING OFF THE DEVICE

Never switch the device off during an examination or whilst in configuration mode. Never disconnect the main power supply when the device is switched on. Failure to comply with these instructions may cause a malfunction of the device and/or loss of data.

## 2.7. CLEANING AND MAINTENANCE

These maintenance operations must not be performed by a third party other than a technician authorized by Echosens.

The opening or modification of the device by any person other than an authorized Echosens technician is strictly prohibited.

No CD ROMs or DVD ROMs other than those provided by Echosens should be inserted into the drive.

The probe must be calibrated periodically. Beyond this period, the manufacturer no longer guarantees the performance characteristics of the probe.

## 2.8. CLEANING

To prevent electric shock, switch off the device and disconnect it from the power supply before cleaning.


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## 2.9. INTERPRETING THE RESULTS

Results must only be interpreted by a physician specializing in liver diseases, who is aware of the patient's pathology and clinical context.


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# 3. MISCELLANEOUS INFORMATION

## 3.1. GUARANTEE

The terms of guarantee are stated in the Echosens terms of sale documents.

For any requests, Echosens is at the disposal of the physician and their assistants and shall, if necessary, pass the aforementioned request on to the competent local representative.

## 3.2. LIABILITY

The information displayed on the FibroScan screen is the result of complex calculations performed by the software application built into the FibroScan. These results are then interpreted by the physician in charge. Under no circumstances, and even if Echosens had been notified, could Echosens be held responsible for the incorrect interpretation of these results; Echosens' liability being limited to making the measurements, displaying them and printing them via the FibroScan.

The data from each examination are saved on the device's hard disk. The user is responsible for saving the data on a regular basis. Echosens cannot under any circumstances be held liable for the partial or total loss of FibroScan data.

## 3.3. ESSENTIAL PERFORMANCE CHARACTERISTICS

The essential performance of the FibroScan device is the medically-usable measurement of liver stiffness. The measurement is taken at 50 Hz shear wave frequency. When the optimum conditions, particularly relating to electromagnetic disturbance, cannot be obtained, the FibroScan device does not display any measurements, but displays a warning message to notify the user that measurements are not possible.

When a stiffness or CAP (Controlled Attenuation Parameter) value is displayed by FibroScan, this value is correct within the range of error specified by Echosens.

Free from the production of unintended or excessive transducer assembly surface temperature.

## 3.4. PRODUCT LIFE

Echosens guarantees the specifications and performance characteristics of the FibroScan device for seven years, provided that all necessary precautions for use and maintenance have been taken in accordance with the recommendations of the user manuals provided.


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## 3.5. REVERSE ENGINEERING

The software license is individual and cannot, under any circumstances, be transferred in any manner to a third party. This software cannot be distributed, reproduced, translated, disassembled, decompiled, analyzed, modified, incorporated or combined with another software application, with the exception of cases allowed by law.

Resale of the software built into the FibroScan is prohibited.

## 3.6. REGISTERED TRADEMARKS

Echosens and FibroScan are registered trademarks of Echosens.

Microsoft Excel and Windows Embedded are registered trademarks of Microsoft Corporation in the United States and other countries.

## 3.7. PATENTED TECHNOLOGY

FibroScan is covered by one or more patents, both in the United States and in other countries.

Patents: www.echosens.com/patents


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# 4. INDICATIONS AND PRECAUTIONS FOR USE

## 4.1. INTENDED USE

The FibroScan and its probes form an active, non-implantable medical device using ultrasound. This device is designed to be used in a physician's office.

The FibroScan system is designed to provide 50 Hz shear wave speed measurements and estimates of tissue stiffness as well as a 3.5 MHz ultrasound coefficient for the Attenuation Parameter (CAP: Controlled Attenuation Parameter) in internal structures of the body.

The FibroScan device is based on Vibration-Controlled Transient Elastography (VCTE$^{TM}$).

The FibroScan probe comprises a single-element ultrasound transducer mounted on the shaft of the electrodynamic transducer. This transducer generates a transient vibration, which in turn generates an elastic shear wave. This wave propagates through the skin, the subcutaneous tissues, and then the liver. During shear wave propagation, the ultrasound transducer performs a series of ultrasound acquisitions (emission/reception) to measure the speed of shear wave propagation (Vs) in m/s. This measurement corresponds to the spatial and temporal average speed of propagation of the shear wave through the liver region of interest, which can be approximated by a cylinder with a diameter of 1 cm and a length of 4 cm (corresponding to approx. 3 $cm^3$).

Additionally, assuming that the liver is a pure elastic, linear and isotropic medium, the device converts shear wave speed Vs into equivalent stiffness E in kPa using the equation $E = 3 \times \rho \times Vs^2$ with $\rho$ the medium density assumed to be 1000 $kg/m^3$. The values for shear wave speed and equivalent stiffness (or Young's modulus) are relative indexes intended only for the purpose of comparison with other measurements performed using FibroScan devices.

Concomitantly, the ultrasound acquisitions are used to assess the Controlled Attenuation Parameter (CAP). Ultrasound attenuation corresponds to the loss of energy as ultrasound propagates through the medium. Due to attenuation, the intensity of emitted ultrasound ($I_0$) decreases exponentially with depth (z): $I_z = I_0 \times \exp(-\alpha(f) \times z)$ where $I_z$ is the ultrasound intensity at depth z and $\alpha$ is the frequency- (f) dependent attenuation coefficient. Ultrasound attenuation depends principally on (i) the ultrasound frequency, and (ii) the properties of the medium of propagation. CAP assesses the value of $\alpha$ at the frequency f = 3.5 MHz and is expressed in dB/m.

Absolute values for these measurements may vary between measurement devices produced by different manufacturers.


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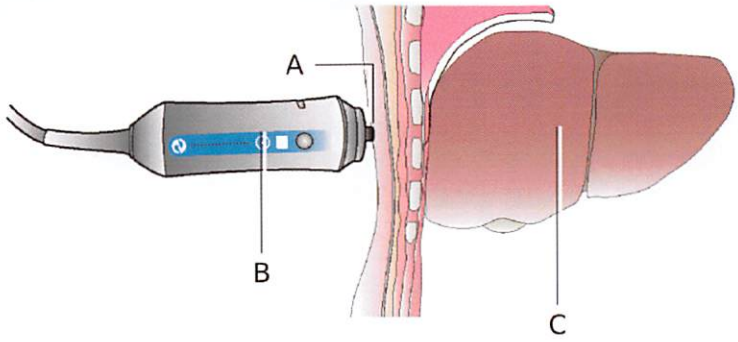
## 4.2. INDICATIONS FOR USE

The FibroScan is indicated for non-invasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as determining a 3.5 MHz ultrasound coefficient for the Attenuation Parameter (CAP: Controlled Attenuation Parameter). The shear wave speed, stiffness, and CAP may be used as an aid in the clinical management of adult patients with liver disease. Shear wave speed and stiffness may be used as an aid in the clinical management of pediatric patients with liver disease.




***How to use a probe: A:*** *Ultrasound transducer.* ***B:*** *Electrodynamic transducer.* ***C:*** *Liver.*

The values obtained must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patient and the potential presence of different factors known to influence liver shear wave speed or equivalent stiffness and CAP. Based on the existing literature, the following table 1 provides a list of parameters known to increase liver shear wave speed and stiffness.

***Table 1:*** *Parameters related to shear wave speed and stiffness.*

| Parameter | Reference |
|---|---|
| Liver fibrosis, cirrhosis | [1-9] |
| Acute hepatitis, inflammation, ALT flares | [10-13] |
| Portal pressure, central venous pressure | [14-16] |
| Extra-hepatic cholestasis | [17] |
| Congestion (heart failure) | [18] |
| Meal intake | [19] |
| Amyloidosis | [20-22] |

For shear wave speed measurement, the intra- and inter-operator agreement has been assessed in a cohort of 200 adult patients with chronic liver disease of various etiologies [23]. The intra-class correlation coefficient was 0.98 both within and between operators. Moreover, in a cohort of 31 NASH children, a 0.96 inter-operator intra-class correlation coefficient was found [24]. This demonstrates that intra-operator reproducibility is excellent for shear wave speed and stiffness measurements, and that changing the operator does not increase measurement variability in either adults or children.

[1] Friedrich-Rust, M., et al., Performance of transient elastography for the staging of liver fibrosis: a meta-analysis. Gastroenterology, 2008. 134(4): p. 960-74.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[2] Musso, G., et al., Meta-analysis: Natural history of non-alcoholic fatty liver disease (NAFLD) and diagnostic accuracy of non-invasive tests for liver disease severity. Annals of Medicine, 2011. 43(8): p. 617-49.

[3] Shaheen, et al., FibroTest and FibroScan for the Prediction of Hepatitis C-Related Fibrosis: A Systematic Review of Diagnostic Test Accuracy. American Journal of Gastroenterology, 2007: p. 1-12.

[4] Shi, K.Q., et al., Transient elastography: a meta-analysis of diagnostic accuracy in evaluation of portal hypertension in chronic liver disease. Liver Int, 2013. 33(1): p. 62-71.

[5] Smith, J.O. and R.K. Sterling, Systematic review: Non-invasive methods of fibrosis analysis in chronic hepatitis C. Alimentary Pharmacology and Therapeutics, 2009. 30(6): p. 557-76. [6] Stebbing, J., et al., A Meta-analysis of Transient Elastography for the Detection of Hepatic Fibrosis. Journal of Clinical Gastroenterology, 2010. 44(3): p. 214-9.

[7] Talwalkar, J.A., et al., Ultrasound-based transient elastography for the detection of hepatic fibrosis: systematic review and meta-analysis. Clinical Gastroenterology and Hepatology 2007. 5(10): p. 1214-20.

[8] Tsochatzis, E.A., et al., Elastography for the diagnosis of severity of fibrosis in chronic liver disease: A meta-analysis of diagnostic accuracy. Journal of Hepatology, 2011. 54(4): p. 650-9.

[9] Lee, C.K., et al., Serum Biomarkers and Transient Elastography as Predictors of Advanced Liver Fibrosis in a United States Cohort: The Boston Children's Hospital Experience. The Journal of pediatrics, 2013. 163(4): p. 1058-64.

[10] Arena, U., et al., Acute viral hepatitis increases liver stiffness values measured by transient elastography. Hepatology, 2008. 47(2): p. 380-4.

[11] Coco, B., et al., Transient elastography: a new surrogate marker of liver fibrosis influenced by major changes of transaminases. Journal of Viral Hepatitis, 2007. 14(5): p. 360-9.

[12] Mueller, S., et al., Increased liver stiffness in alcoholic liver disease: differentiating fibrosis from steatohepatitis. World Journal of Gastroenterology, 2010. 16(8): p. 966-72.

[13] Sagir, A., et al., Transient elastography is unreliable for detection of cirrhosis in patients with acute liver damage. Hepatology, 2008. 47(2): p. 592-5.

[14] Carrión, J.A., et al., Transient elastography for diagnosis of advanced fibrosis and portal hypertension in patients with hepatitis C recurrence after liver transplantation. Liver Transplantation, 2006. 12(12): p. 1791-8.

[15] Millonig, G., et al., Liver stiffness is directly influenced by central venous pressure. Journal of Hepatology, 2010. 52(2): p. 206-10.

[16] Vizzutti, F., et al., Liver stiffness measurement predicts severe portal hypertension in patients with HCV-related cirrhosis. Hepatology, 2007. 45(5): p. 1290-7.

[17] Millonig, G., et al., Extrahepatic cholestasis increases liver stiffness (FibroScan) irrespective of fibrosis. Hepatology, 2008. 28(5).

[18] Lebray, P., et al., Liver stiffness is an unreliable marker of liver fibrosis in patients with cardiac insufficiency. Hepatology, 2008. 48(6): p. 2089.

[19] Mederacke, I., et al., Food intake increases liver stiffness in patients with chronic or resolved hepatitis C virus infection. Liver International, 2009. 29(10): p. 1500-6.

[20] Janssens, E., et al., Hepatic amyloidosis increases liver stiffness measured by transient elastography. Acta Gastroenterologica Belgica, 2010. 73(1): p. 52-4.


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[21] Lanzi, A., et al., Liver AL amyloidosis as a possible cause of high liver stiffness values. European Journal of Gastroenterology and Hepatology, 2010. 22(7): p. 895-7.

[22] Loustaud-Ratti, V.R., et al., Non-invasive detection of hepatic amyloidosis: FibroScan, a new tool. Amyloid, 2011. 18(1): p. 19-24.

[23] Fraquelli, M., et al., Reproducibility of transient elastography in the evaluation of liver fibrosis in patients with chronic liver disease. Gut, 2007. 56(7): p. 968-73.

[24] Nobili, V., et al., Accuracy and reproducibility of transient elastography for the diagnosis of fibrosis in pediatric nonalcoholic steatohepatitis. Hepatology, 2008. 48(2): p. 442-8.

## 4.3. PROBE AND EXAMINATION SELECTION CRITERIA

The recommendations for choosing the probes are defined by the patient's morphological data:

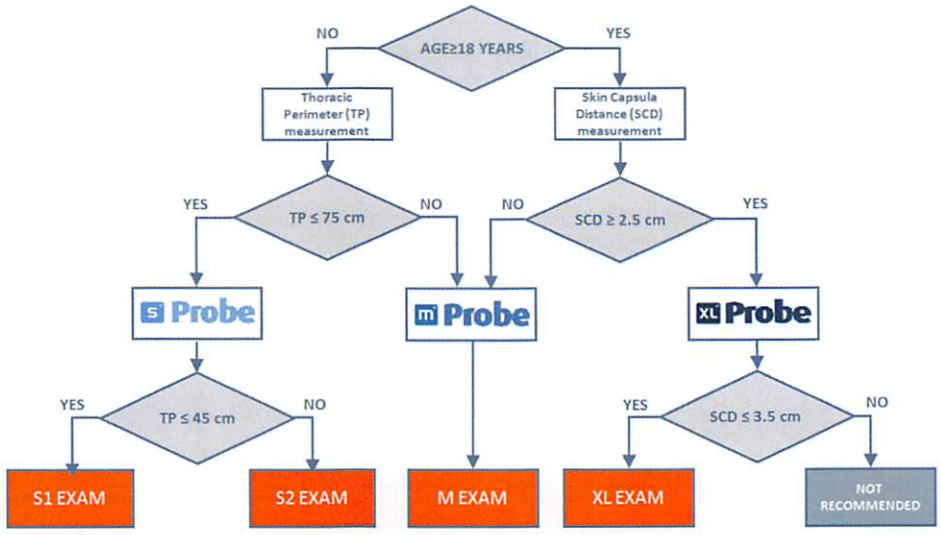
- TP: Thoracic Perimeter measured at the xiphoid using a tape measure.
- SCD: Skin-to-Capsule Distance assessed with an ultrasound scanner or by the automatic probe selection tool.

When using ultrasound, SCD should be measured at the point where the shear wave speed is measured with a pressure similar to the one used with the FibroScan probe.

In case of using the automatic probe selection tool, please refer to chapter 6.5.11. Examination type selection area.

Compressing the soft tissues to reduce the SCD is not recommended.

Four types of examination are available: S1, S2, M and XL. They correspond to specific measurement depths that take into account the liver's depth beneath the skin.




In every case, Echosens recommends performing 10 valid FibroScan measurements.

Use of the S+ probe is not approved for patients over 18 years old. Use of the M + probe is not approved for patients under 14 years old. Use of the XL+probe is not approved for patients under 18 years old.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## 4.4. PRECAUTIONS FOR USE

The following instructions must be followed in order to ensure patient safety. The FibroScan should not be used in the following situations:

- On any organ other than the liver. The eyes and mucosa must absolutely be avoided.
- On patients with active implants such as pacemakers, defibrillators, pumps, etc.
- On wounds.
- On pregnant women.

Moreover, the presence of ascites between the probe and the liver may prevent from obtaining measurements with the device.

The clinical personnel must follow normal safety procedures.

The FibroScan examination should be performed carefully using the principle of ALARA (As Low As Reasonably Achievable).

## 4.5. USER TRAINING

Only persons having received training in the use of the FibroScan and in possession of a user certificate are authorized to conduct an examination using the FibroScan. Training is essential for correct equipment use and in order to obtain reliable and reproducible measurements.

This manual is not intended to provide user training.

## 4.6. ELECTRICAL SAFETY

The FibroScan is manufactured and tested in accordance with IEC electromagnetic compatibility (EMC) and electrical safety standards. It leaves the plant in full compliance with safety and performance requirements. In order to maintain this compliance and to guarantee the safe use of this medical device, the user must comply with the indications and symbols contained in this manual.

Refer to the warnings in Chapter 2 concerning electrical safety.

Prior to installation, ensure that the operating and mains voltage values match.

The electrical power cable provided must be connected to the FibroScan mains connector and to a grounded socket. Correct grounding can only be guaranteed if the FibroScan is connected to a socket compliant with safety standards.

Safe use is no longer guaranteed in the following main, non-exhaustive cases:

- the device is visibly damaged,
- the device is inoperative,
- after prolonged storage in unfavorable conditions,
- after serious damage incurred during transport,
- in the presence of flammable or anesthetic gases. This may cause an explosion. Do not take the device to the operating room.


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If the FibroScan can no longer be used safely, the device must be decommissioned. Steps must be taken to prevent its inadvertent use. The medical device must only be inspected by authorized technicians.

## 4.7. MAINTENANCE-RELATED SAFETY

For all maintenance operations, the physician and their appointees should contact Echosens, who will send an authorized technician.

For correct and safe use and any maintenance operations, personnel must comply with normal safety procedures.


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# 5. EXTERNAL PRESENTATION

## 5.1. HARDWARE SUPPLIED

When opening the package, ensure the contents match the following list:

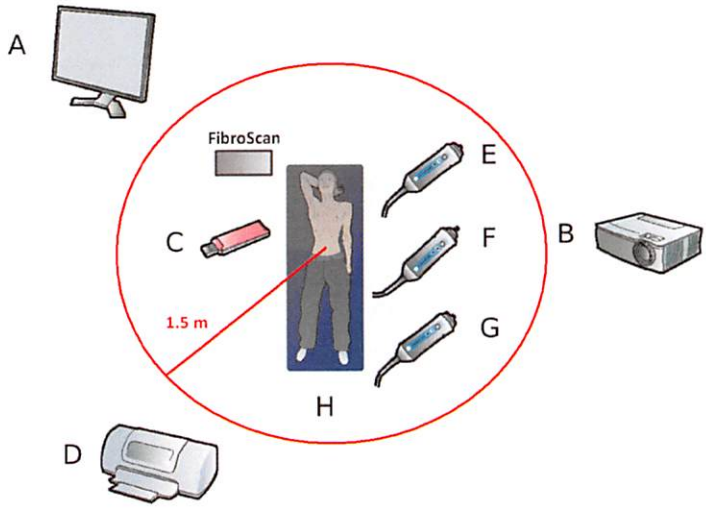
- FibroScan device installed
- Power cables according to country
- Case(s) fitted with probe(s)
- Sealed envelope (Windows EULA license and this user manual)
- Software installation CD ROM
- Set of four fuses, type 5x20 T2.0AH 250V

## 5.2. ACCESSORIES

The available accessories are:

- $S^+$ probe
- $M^+$ probe
- $XL^+$ probe

Set of elements that can be connected to the FibroScan device:




***Devices not included:*** ***A:*** *DVI-I screen.* ***B:*** *Overhead projector.* ***C:*** *USB storage device.* ***D:*** *USB printer.*

***Accessories:*** ***E:*** *$S^+$ probe.* ***F:*** *$M^+$ probe.* ***G:*** *$XL^+$ probe.* ***H:*** *Other accessories.*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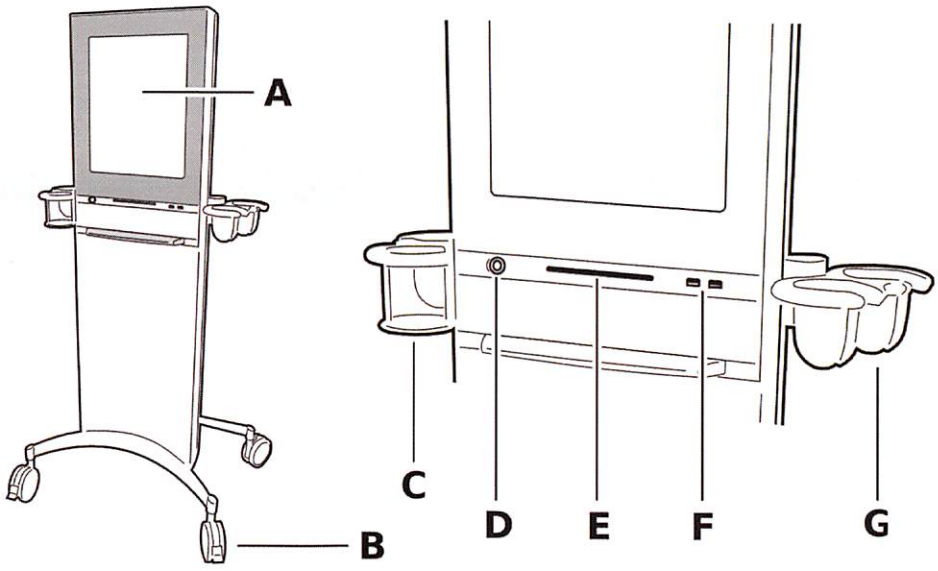
## 5.3. FRONT VIEW

The device contains the electrical power supply, dedicated electronics and a computer. It also supports a monitor, three probe holders, and a gel holder.

The following figure presents the device's various user-accessible parts.




***General arrangement of the FibroScan device:*** ***A:*** *Touch screen.* ***B:*** *Caster with brake.* ***C:*** *Gel holder.* ***D:*** *Standby button with power indicator.* ***E:*** *CD ROM / DVD ROM drive.* ***F:*** *Computer sockets.* ***G:*** *Probe holder.*

### Standby button

This button is enabled only when the main switch, located at the rear of the device, is set to "I".

The button flashes when power is on.

Press this button once to load the application; the built-in indicator light turns green. After a few seconds, the home window is displayed.

Press this button again to close the application; the built-in indicator light and monitor are both turned off. This is the usual state when the FibroScan will not be in use for a short time (between two groups of patients, for example). The FibroScan consumes very little power in this mode.

### The screen and the software

This is a 17- or 19-inch color LCD touch screen, depending on the model year.

To protect the screen from any risk of damage, make sure not to hang the power cable on the top of the device.

The FibroScan runs on dedicated software.

The software is automatically launched when the FibroScan is switched on. It is used to:

- perform examinations,
- manage examinations in archives.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### Computer connectors

Two USB 2.0 sockets : To connect an external hard disk for backups, a USB key, or a USB printer.

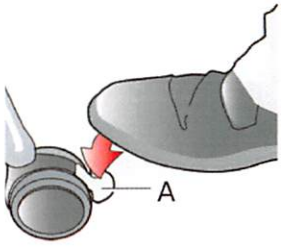
### CD ROM – DVD ROM drive

This drive can be used to reinstall or update the software.

Refer to the warning in Chapter 2 concerning cleaning and maintenance.

### Casters and brakes

The two front casters are fitted with a brake. The brake is blocked by pressing the latch. The caster is released by lifting this same latch.




***View of a caster with brake: A:*** *Caster brake.*

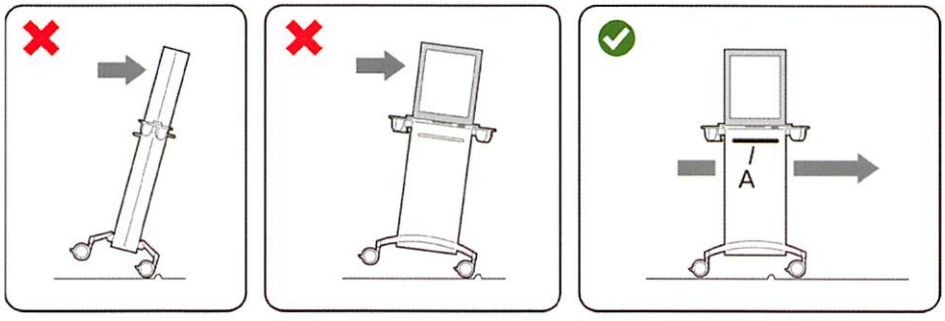
### Moving the device

Always unlock the brakes before moving the device.

Do not push or lean on the top of the FibroScan device.

To avoid tipping the FibroScan when moving it, move it slowly sideways and steer it firmly by holding the decorative rods on the front and back of the device.

To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.




***Moving the device: A:*** *Decorative rod.*

## 5.4. REAR VIEW

The following figure presents the device's different user-accessible parts.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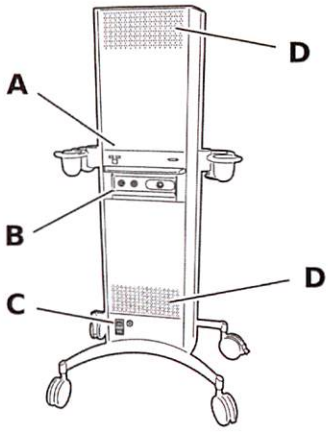
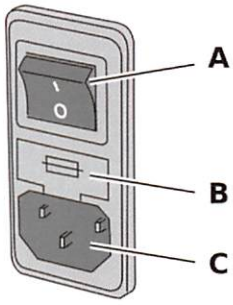



***Rear view: A:** Computer sockets. **B:** Probe sockets. **C:** Power connector. **D:** Perforated ventilation plates.*

### Power connector

The FibroScan must be connected to a 100V to 240V single phase AC 50-60 Hz grounded power outlet via the power cable connected to the socket at the base of the chassis.




***View of the main switch and connection outlet: A:** Main switch. **B:** Location of the fuses. **C:** Mains lead connection socket.*

### Main switch

This switch has two positions:

- Position 0: no voltage is present in the internal circuits of the FibroScan, meaning that it consumes no electrical energy. This is the usual position when the FibroScan is no longer to be used (at the end of the day for example).
- Position 1: the internal electrical circuits of the FibroScan are powered by the AC power supply. This is the FibroScan's working position.

This switch assembly has a removable part. It provides access to the two FibroScan protection fuses.

The bottom part of the switch device receives the power cable plug connection outlet.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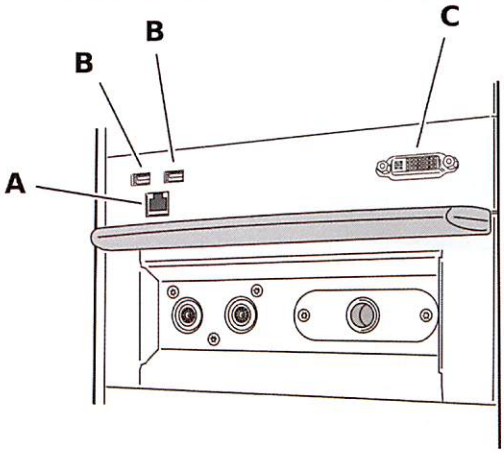
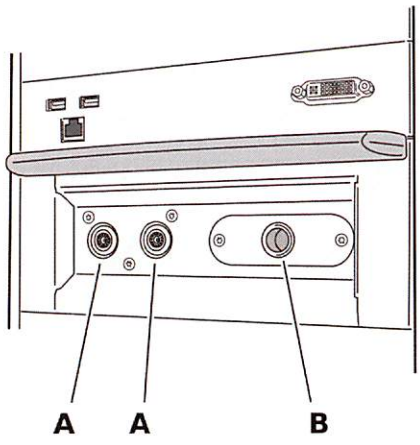
### Computer connectors




***Location of computer connectors: A:*** *Ethernet.* ***B:*** *2 USB 2.0 ports.* ***C:*** *DVI-I output.*

- Ethernet connector: also used for connectivity. Used by Echosens maintenance staff.
- Two USB 2.0 sockets : To connect an external hard disk for backups, a USB key, or a USB printer.
- DVI-I output : This output is used to connect an additional monitor (e.g. an overhead projector). The maximum distance between the FibroScan and the additional monitor is of approximately 1.80 meters.

### Probe connectors




**Location of probe sockets: A:** Probe connector. **B:** Location for the connector of the unconnected probe.

Location (B) is not operational. It protects the connector of the unconnected probe.

The probe connectors are fragile.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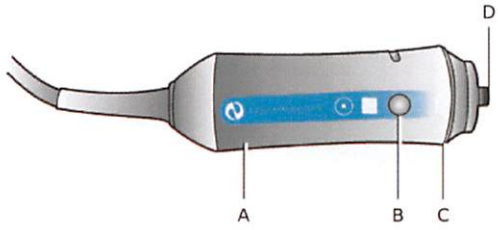
## 5.5. DESCRIPTION OF PROBES

The probe contains an electrodynamic actuator (vibrator), an ultrasound transducer and a measurement trigger button.




***Probe: A:** Electrodynamic actuator. **B:** Measurement button. **C:** Indicator light (LED). **D:** Ultrasonic transducer. **E:** Probe lead.*

The ultrasound transducer of the probe is a "Type B" applied part, and is the only component of the FibroScan device in contact with the patient.

### Measurement button

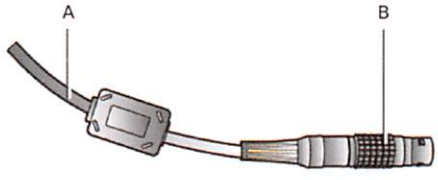
As soon as this button is pressed (if sufficient force is placed on the transducer), the electrodynamic transducer generates a shear wave that painlessly impacts the patient's skin. At the same time, the ultrasound transducer performs a series of acquisitions (emission/ reception) to measure the propagation speed of this shear wave. Acquisition lasts less than one tenth of a second.

### Indicators

The indicator lights (LEDs) display a status as follows:

- Lit up blue during FibroScan start-up and when standing by to launch an examination.
- Flashing blue lights for the probe selected when an examination starts.
- Not lit up during an examination when the operator is not applying correct pressure on the patient's body.
- Lit up blue during an examination when the operator is applying the correct pressure to the patient's body. It is however strongly recommended that you view the pressure exerted by looking at the on-screen pressure indicator.

### Lead




***Probe lead: A:** Connection cable. **B:** Connector.*

This 1.5 m lead connects the probe to the FibroScan by means of a multi-pin jack with guide pin.

The probe transducer, the probe jack, and the FibroScan connector are fragile elements and must be handled with care.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The probe jack has a red dot that should be aligned with the red dot on the FibroScan socket before insertion.

The serial number marked on the connector identifies the probe uniquely.


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# 6. SOFTWARE INTERFACE

## 6.1. HOME SCREEN

The software loaded when the FibroScan device is started up is used to:

- perform examinations,
- print the results,
- manage the archives,
- export the data in several formats.

If the software is connected to the hospital network (optional):

- import the list of patients,
- export the results of the examination.

When the device is switched on, the home screen is displayed.

### Description of the home menu

Access to FibroScan configuration. See the Configuration section.

Access to the patient file archives..

Access to the examination.

The following messages can be displayed in the home window:

- No probe connected
- Probe out of calibration (see the Probe Calibration section)

Return to the home screen by clicking the Home button:


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## 6.2. USING THE KEYPAD

The keypad is displayed whenever an input is required.

### Description of keypad:

Shift.

Display the special characters keypad.

Delete the character immediately before the cursor.

Tab. To move from one input field to another.

Special characters are accessible by pressing and holding a letter. Example :

## 6.3. LOGIN WINDOW

If secure session opening has been enabled, all the users are displayed. The login window allows a secured access to the patient data in the device.

The enabling of secure session opening and the user accounts are configurable. See the Configuration section.

### User name/Password

The user name and password are defined when the device is installed. To change the password, see the Configuration section.

Beyond a certain idle time, the current user is disconnected and the application returns to the home window.

This duration is configurable (see Configuration/General)


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## 6.4. STATUS BAR

When a user is logged in, a status bar located at the top of the home screen gives information about the device. This includes:

Percentage of disk space available.

Results of FibroScan examination waiting for network transfer.

Options enabled: CAP, Clinical Mode, Anonymization of automatic export to USB.

Profile type and user name of connected user.

Pay per Use key input.

Device date and time.

Refer to the Configuration chapter to modify these parameters.


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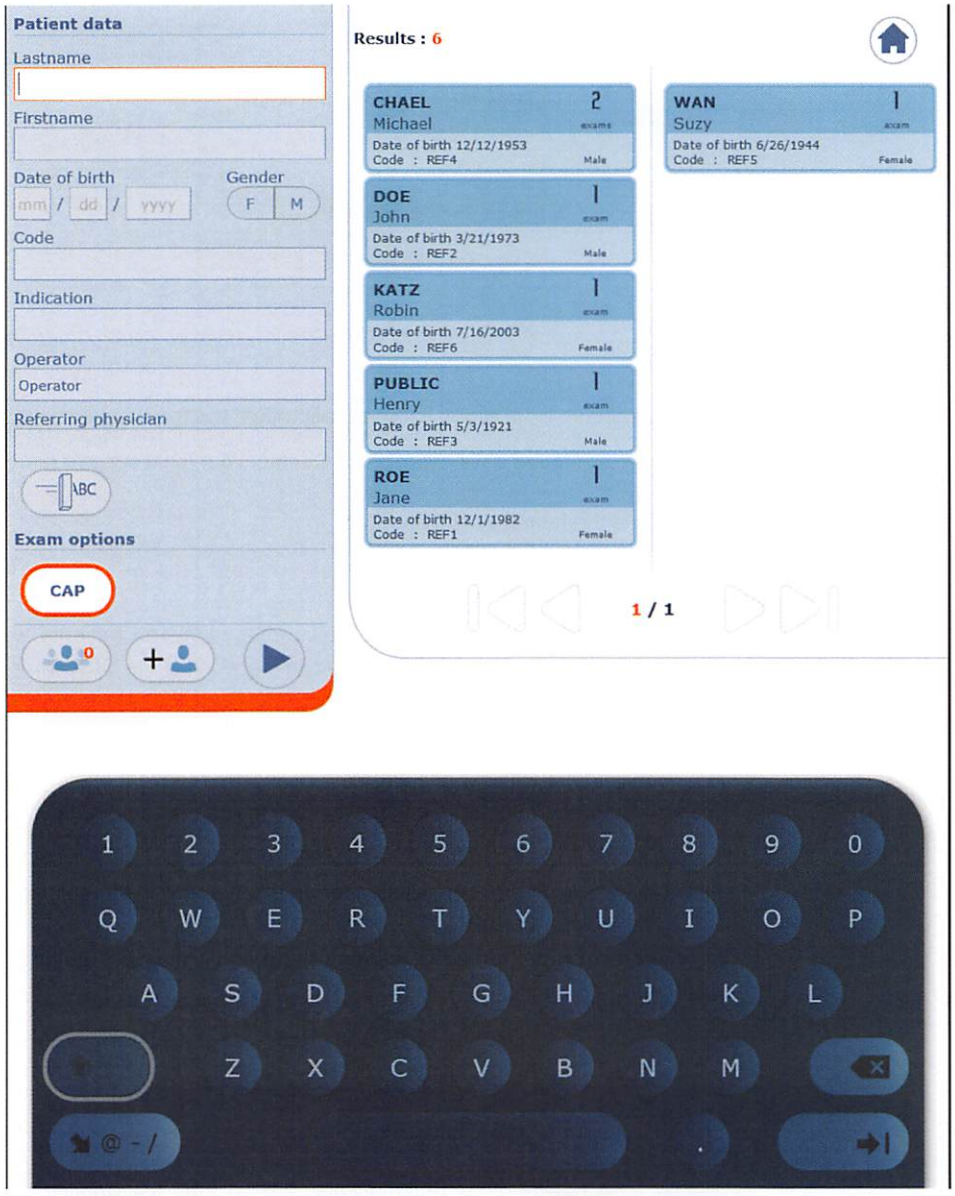
## 6.5. THE PATIENT RECORD SCREEN

If the patient exists in the patient list, the data will be displayed automatically after the name is entered. Select the patient.




Complete the fields. At least the 'Name' or 'Code' field must be filled in to start the examination.

CAP — Enables/disables the CAP option for the examination about to start.

Raw — Enables/disables the saving of Raw Data for the examination about to start (available only if Clinical Mode was enabled in the Configuration).

Saving Raw Data can slow the application down considerably. Enable it only for clinical studies that explicitly require it.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Add the selected patient to the list of patients waiting for an examination. An examination can be performed on this patient later.

Shows/hides the worklist

Deletes the content of the fields.

Cancels the patient entry.

Starts the examination.

After data input, if the probe is out of calibration, the following message appears:

- Probe calibration days overdue: n. Contact your local support team.

Where n is the number of days.

## Patient waiting list

The patient waiting list (Worklist) allows information on patients waiting for a FibroScan examination to be retrieved on the hospital network. If the DICOM or FibroView options are enabled, this information is entered just once and then sent automatically at every stage relating to the examination.

If a Worklist-type DICOM or FibroView connection (patient waiting list) is enabled (Refer to the Configuration chapter, Connectivity tab),the device automatically queries the network to import the patients waiting for an examination.

However, to import a patient waiting for an examination in the coming days, a manual patient search must be performed by clicking the magnifying glass button in the Worklist window.

Deletes the selected patient from the worklist.

A patient file is automatically deleted from the worklist if an examination with at least one valid measurement has been taken, or if the patient file has been on the worklist for more than three days.


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## 6.6. ACQUISITION SCREEN

The main data displayed in an acquisition window are presented below.

The CAP value (dB/m) is displayed only if the option is installed.

After five minutes of idle time during an acquisition, a message tells the user, who then has five additional minutes before the examination is automatically halted. Beyond this time, if no action has been taken, the examination is saved and then stopped.


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The acquisition window comprises the following elements:

### 6.6.1. Patient data

Shows/Hides the patient data.

### 6.6.2. Ultrasound images

**TM and Amplitude Modes**

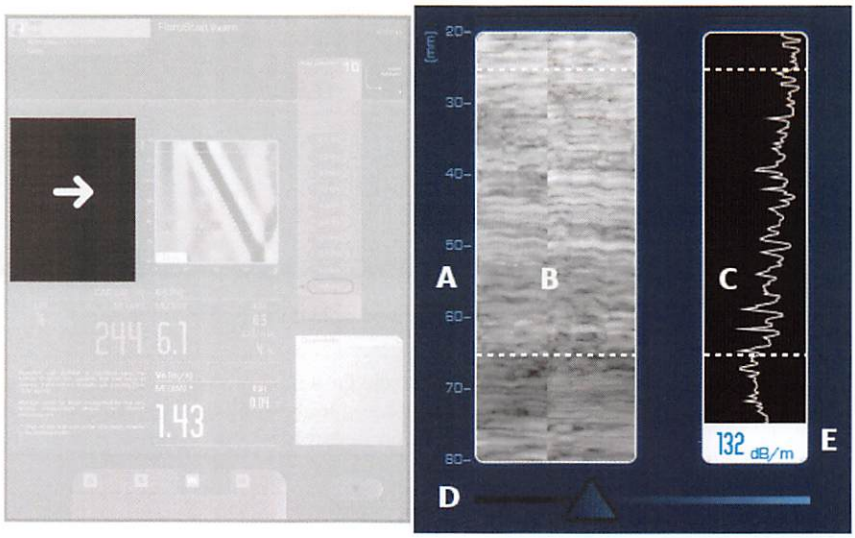


***Image in TM (left) and Amplitude (right) modes:*** ***A:*** *Depth explored (mm).* ***B:*** *Ultrasound signal represented in TM (Time-Motion) mode.* ***C:*** *Ultrasound signal represented in A (Amplitude) mode.* ***D:*** *Display gain adjustment.* ***E:*** *Current CAP value.*

*Note: The CAP value is displayed only if the option is installed.*


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As soon as the probe makes contact with the skin, i.e. when a pressure change is detected, the ultrasound transducer makes ultrasound acquisitions.

The system displays two ultrasound images used to locate a zone that satisfies the measurement criteria:

- One in Time-Motion (TM) mode, two-dimensional grayscale image.
- The other in A mode (ultrasound signal amplitude).

The gain on the display of both modes can be adjusted using the cursor under the ultrasound images.

These two modes serve to ensure that the probe is correctly positioned to perform a measurement on a sufficiently thick portion of liver, visible throughout the explored depth. They also allow the operator to ensure that the measurement will not be disrupted by the presence of structures not of interest, such as blood vessels.

### Liver targeting tool

***Liver targeting tool: A:*** *Liver indicator history.* ***B:*** *Real-time liver indicator.*

The user can use the liver targeting tool to position the probe at an appropriate point for measuring the liver stiffness and/or CAP.

As soon as the probe is in contact with the patient's skin, the liver targeting tool characterizes the quality of the ultrasound signals propagating in the liver using a color scale.

***Color scale: Black:*** *The quality of the ultrasound signals is low.* ***Green:*** *The quality of the ultrasound signals is high.*

The greener the liver indicator, the higher the quality of the ultrasound signals, and the better the position of the measurement point.

Liver targeting tool is available with the $M^+$ and $XL^+$ probes only.


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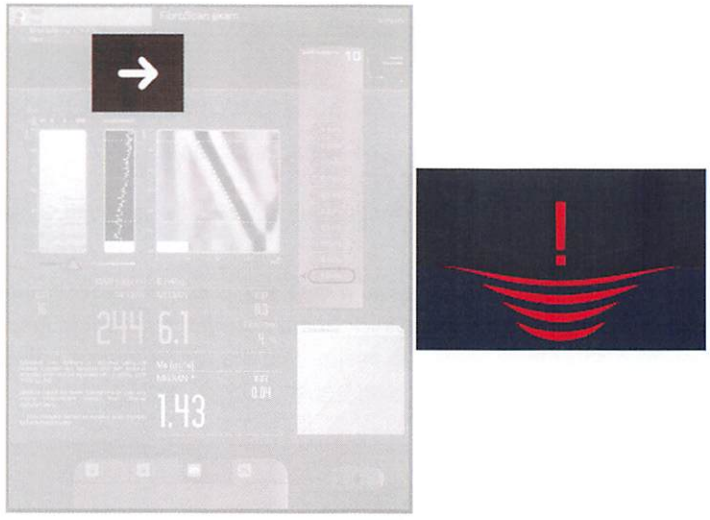
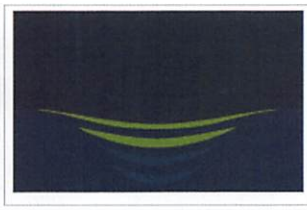
### 6.6.3. Pressure indicator



The probe contains a sensor that measures the pressure applied by the operator to the patient. The pressure level is given by:

- The software: Pressure indicator (green/orange/red).
- The probe: Blue LEDs.

Measurements may only be made when the pressure indicator is in the green zone.

| | | |
|---|---|---|
| | |  |
| *Pressure too high (red).* | *Pressure too low (orange).* | *Correct pressure (green).* |
| *Probe LEDs off.*<br>*Measurement disabled.* | *Probe LEDs off.*<br>*Measurement disabled.* | *Probe LEDs ON.*<br>*Measurement possible.* |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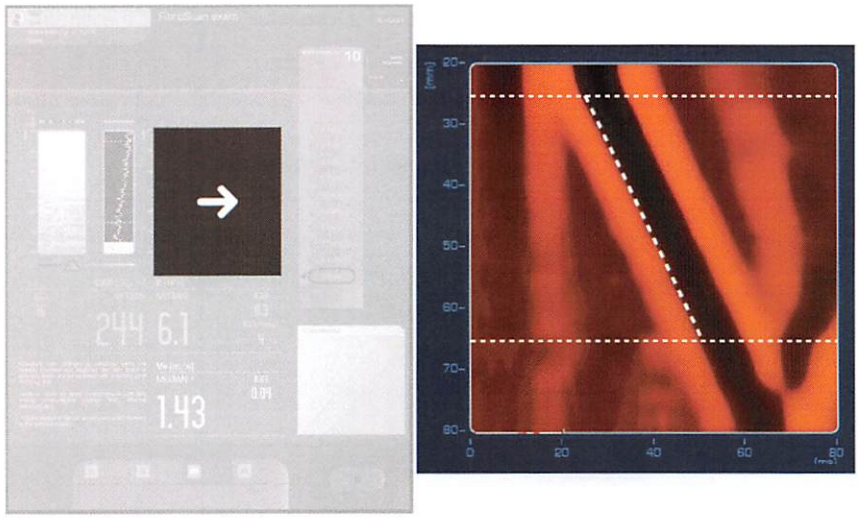
### 6.6.4. Shear wave propagation map

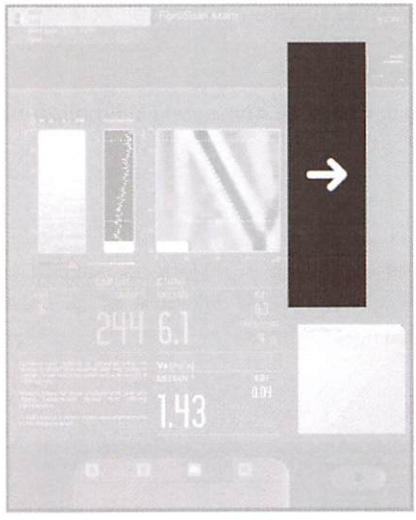


This image is displayed once the measurement is complete. It represents the levels of liver deformation generated by the propagation of the shear wave as a function of time (horizontal axis in milliseconds) and depth (vertical axis in millimeters).

The shear wave speed value is displayed if the measurement is valid.

The color scale indicates deformations (compression or expansion). Black areas correspond to negative deformation and pale areas to positive deformation. The black strip through the image represents deformations associated with the passage of the shear wave, which penetrates progressively deeper with time.

### 6.6.5. Counters: Valid and invalid measurements



**Valid measurements**

From top to bottom: First to last measurement in kPa.

When the number of valid measurements is equal to 1, the IQR and the IQR/median ratio are undefined. They are therefore not displayed.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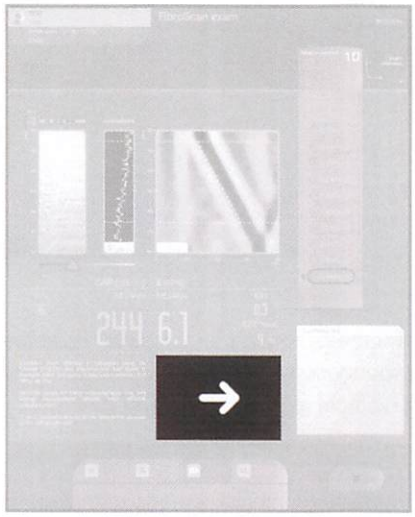
### Invalid measurements

The measurement is automatically rejected by the algorithms if the pulse sent out by the transducer could not be delivered successfully and/or if the shear wave propagation maps are not satisfactory.

The message 'INVALID' is then displayed above the shear wave propagation map.

## 6.6.6. *Shear wave speed results area*



### Median

Shear wave speed is expressed in meters per second (m/s). This value is the median of all valid measurements performed during the examination.

If the repeat measurement is invalid, the median is not recalculated. To obtain a reliable and representative shear wave speed measurement in the liver, **at least 10 valid measurements must be taken.**

Refer to the warning in Chapter 2 concerning interpretation of the result.

### Interquartile range (IQR)

The interquartile range (IQR) is expressed in meters per second (m/s). It represents the interval around the median within which will fall 50% of all valid measurements. It is recalculated after each new valid measurement.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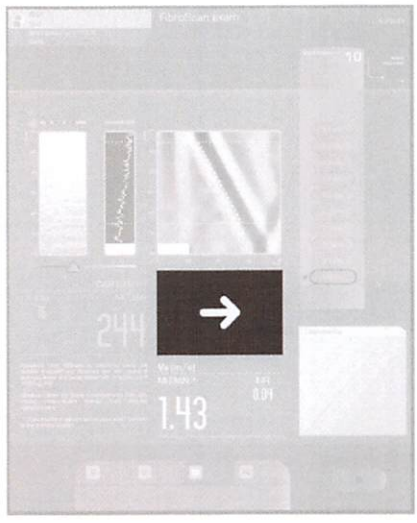
### 6.6.7. Stiffness results area




#### Median

Stiffness is expressed in kilopascal (kPa). This value is the median of all valid measurements performed during the examination.

If the repeat measurement is invalid, the median is not recalculated. To obtain a reliable and representative liver stiffness measurement, **at least 10 valid measurements must be taken.**

Refer to the warning in Chapter 2 concerning interpretation of the result.

#### Interquartile range (IQR)

The interquartile range (IQR) is expressed in kilopascal (kPa). It represents the interval around the median within which will fall 50% of all valid measurements. It is recalculated after each new valid measurement.

#### IQR/Median

This value, expressed as a percentage, is the ratio of the IQR to the median stiffness. It is recalculated after each new valid measurement.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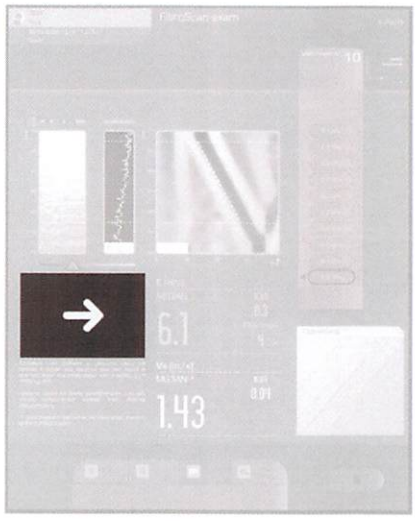
### 6.6.8. CAP result zone (option)




*Note: The CAP value is displayed only if the option is installed.*

The CAP is displayed with the M+ and XL+ probes only.

#### Median

The CAP (Controlled Attenuation Parameter) is expressed in decibels per meter (dB/m). This value is the median of all valid measurements performed during the examination.

The CAP is calculated when the stiffness measurement is valid.

Refer to the warning in Chapter 2 concerning interpretation of the result.

#### Interquartile range (IQR)

The interquartile range (IQR) is expressed in decibels per meter (dB/m). It represents the interval around the median within which will fall 50% of all valid measurements. It is recalculated after each new valid measurement.

### 6.6.9. Deleting measurements

Some or all of the measurements in the current examination may be canceled at any time during the examination. The patient's data, displayed in the left-hand part of the window, are saved.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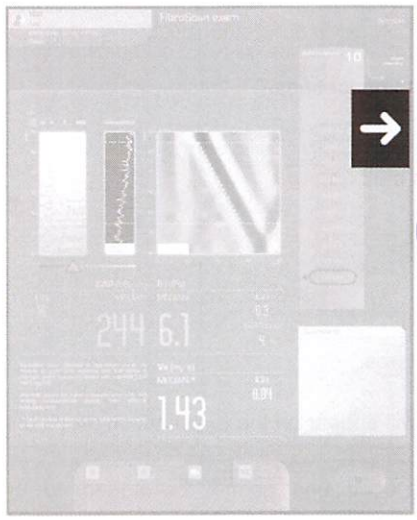
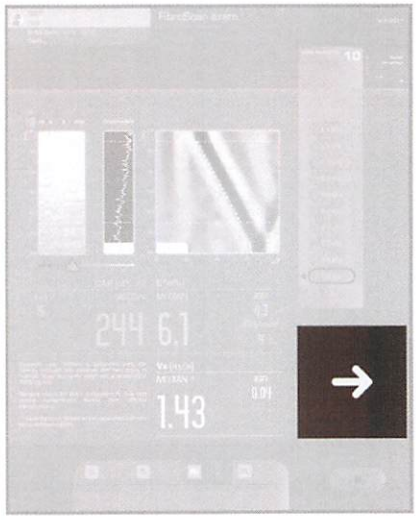


Press the last measurement to be deleted and then the following button:

A confirmation request is displayed and indicates the number of measurements remaining if deletion is confirmed.

Refer to the warning in Chapter 2 concerning deletion of measurements.

### 6.6.10. Adding a comment



You can add comments to the current examination :

- Press the 'Comments' field,
- Enter comments using the touchpanel.

Information entered in the 'Comments' field will appear on the examination result printout.

The 'Comments' field cannot be added to or modified during an examination review.

### 6.6.11. Integrate the measurement conditions

If the option is enabled in Configuration, the conditions under which the examination was conducted can be filled in immediately after finishing the examination. The following input fields are available: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- patient weight,
- patient height,
- observance of dietary recommendations,
- patient position,
- measurement point search method,
- narrow intercostal space,
- thick subcutaneous wall,
- quality of ultrasound signal,
- presence of vascular structures.

The measurement conditions will appear on the examination result printout.

The measurement conditions cannot be added to or modified during an examination review.

### 6.6.12. Message area

The following main messages can be displayed above the elastogram.

Connect the probe.

Replace the probe.


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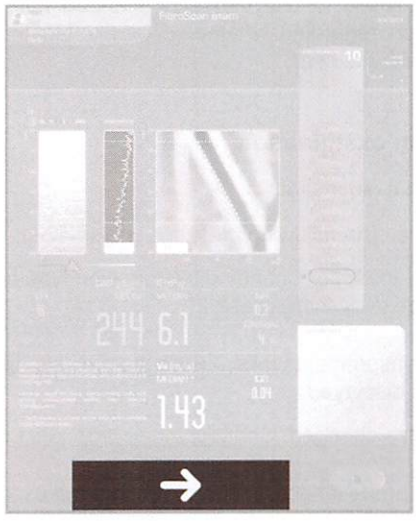
Calibrate the probe.

Electromagnetic disturbances.

Overheating.

### 6.6.13. Examination type selection area

The examination type selection criteria according to patient morphology are described in the section on 'Criteria for selecting the probe and the type of examination'.




If the $S^+$ probe is connected, select examination type S1 or S2.

If only the $M^+$ or $XL^+$ probe is connected, the corresponding examination type is selected automatically by the device software.

If several probes are connected, choose the examination type.

#### Automatic probe recommendation

The automatic probe recommendation tool is based on the Skin-to-Capsule Distance – (SCD) measurement using ultrasound signals received by the device's probe. This feature operates in real time as soon as the probe detects ultrasound signals (probe in contact with patient's skin).

This tool functions for the $M^+$ and $XL^+$ probes only.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The result of this tool is displayed at the bottom of the screen and may be one of the following three cases:

1. 'Recommended probe: in progress': the tool cannot currently measure the SCD because the probe is not correctly positioned in front of the liver and/or the ultrasound signals are of poor quality.
2. 'Recommended probe: M': The tool measures a SCD that justifies the use of the $M^+$ probe. The box containing the M examination type icon flashes.
3. 'Recommended probe: XL': The tool measures a SCD that justifies the use of the $XL^+$ probe. The box containing the XL examination type icon flashes.

If the tool is able to recommend a probe (case 2 or 3), two situations are possible:

- The probe currently in use is the recommended probe: The operator continues the examination without changing probes and, if they wish, can confirm the probe choice by pressing the icon of the examination type concerned. The probe recommendation tool is then disabled until the end of the current examination.
- The probe currently in use is not the recommended probe: The operator changes the probe by applying the procedure explained in the paragraph below.

Be sure to use enough gel for this tool to function properly.

You are strongly advised to use the recommended tool, to guarantee reliable results. The decision regarding whether or not to apply this recommendation, however, remains with the user.

### Change of probe during an examination

To change the probe during an examination: :

1. Select the new probe type. The following message is displayed:
   - Change of examination type. Changing examination type causes all previous measurements to be definitively erased.
2. Click OK (warning: all measurements taken using the previous probe will be deleted), the following message is displayed:
   - Examination type has changed. Connect the appropriate probe to continue.
3. Connect the appropriate probe if necessary and resume the examination.


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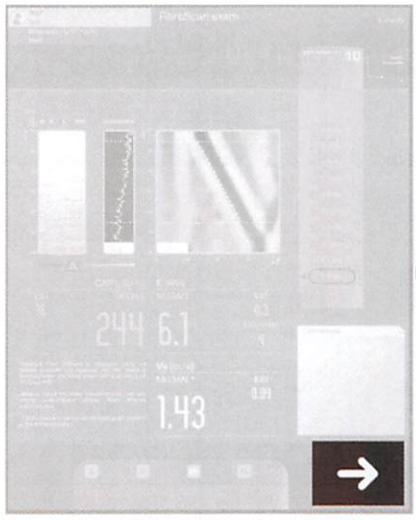
### 6.6.14. View and print the result of the examination



Press the button to end the examination.

The result of the examination is displayed.

**Description of contextual buttons:**

Back to the home window.

Prints the patient examination result.

Exports the patient examination result in FIBX format (a proprietary FibroScan format) to a removable USB storage device.

Exports the patient examination report in PDF format to a removable USB storage device.

Starts a new examination.

If the DICOM option is enabled, in case of failure of automatic examination result export to the DICOM network, the following button is displayed

.

Click this button to try exporting again.

Note that this retry can also be requested via the status bar in the home window.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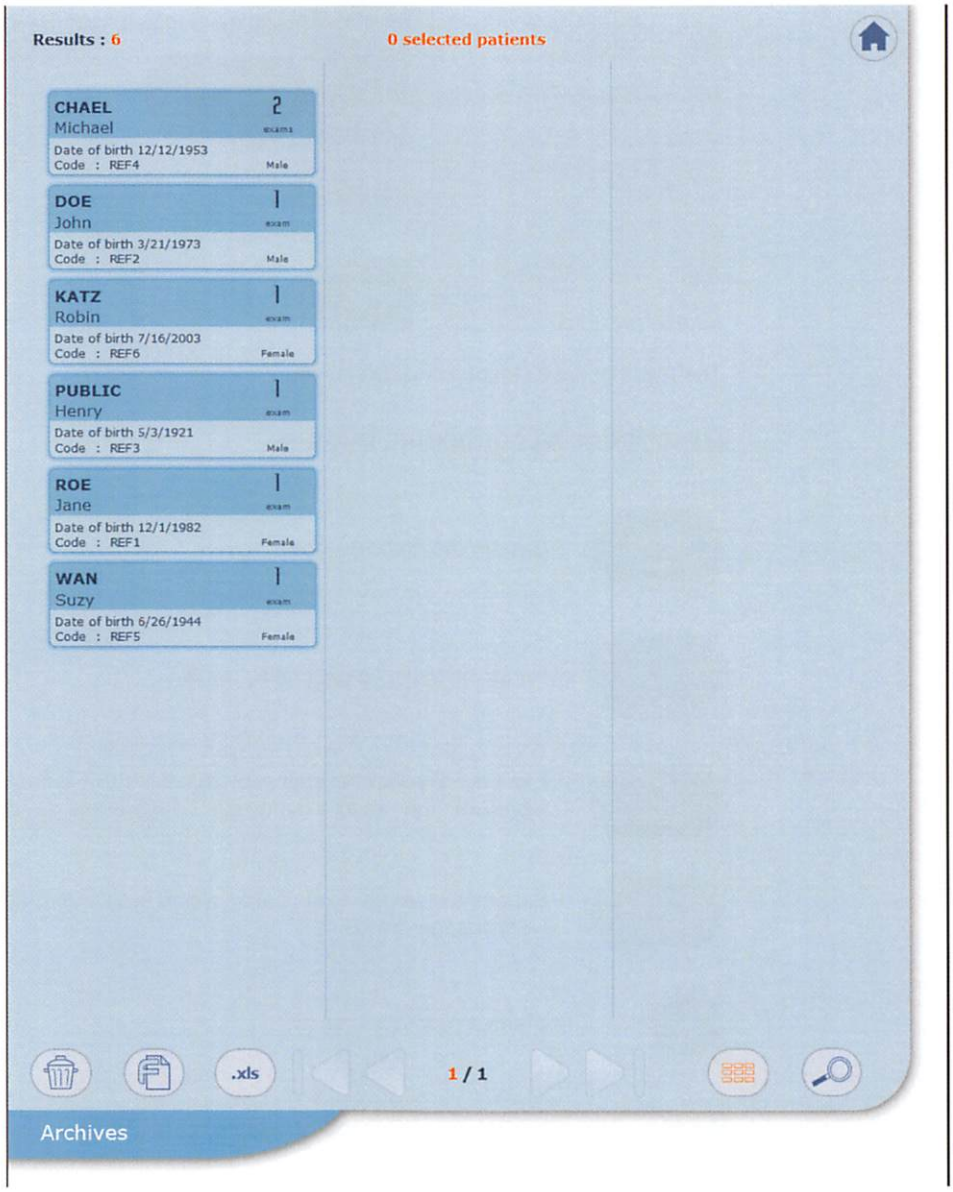
## 6.7. MANAGEMENT OF PATIENT FILE ARCHIVES

To display the patient file archives, press the button in the home screen.




Folder selection when a keyboard is connected: [CTRL]+click to select non-consecutive files, [SHIFT]+click the first and last to select a series of files, and [CTRL]+[A] to select all files.

Deletes the selected files.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Exports the selected examination files to a file in FIBX format on a removable USB storage device. You can export the last examination or all the examinations for one patient.

Exports all the results from all files to a file in XLS format on a removable USB storage device.

Displays the next or previous page of archives.

Displays the last or first page of archives.

Refines the advanced file search.

Selects all patient files displayed.

Closes the screen and displays the home screen (keyboard shortcut: [Esc] key).

**Excel file**

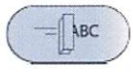
The file is generated in the root of the removable USB storage device. The file name contains:

- the serial number of the device,
- the date and time the Excel file was created.

*The Excel file comprises two data sheets (Data and Parameters).*

### 6.7.1. Advanced file search

Enter one or more search criteria. The list of matching files is displayed.




Deletes the input.

Closes the advanced search.

Opens the examination of the displayed patient.

### 6.7.2. Select and view a patient file

To view the examination summary for a patient, click the label and then .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To view the details of an examination, click the summary of the examination.

### 6.7.3. Details of the examination

To display the measurements, click a value in the list of valid measurements.

**Description of contextual buttons:**

Lets you view the previous examination or the next examination for the patient (keyboard shortcut: left arrow or right arrow).

Back to the Archives screen.

Deletes the examination.

Prints the result of the examination.

Exports the result of the examination to a file in FIBX format.

Exports the result of the examination to a file in PDF format.

Exports the result of the examination on the DICOM network.

Starts a new examination.

Displays the previous or next result in the list of measurements (keyboard shortcut: Up or down arrows). Displayed only in the presence of more than 12 measurements.


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# 7. STANDBY AND SHUTTING DOWN THE DEVICE

## 7.1. BETWEEN SESSIONS

Turn the device off by pressing the standby button in the bottom left-hand corner of the monitor or the shutdown button on the interface.

## 7.2. AT THE END OF THE DAY

Always shut the device down by applying the following sequence:

1. Turn the FibroScan off by holding down the standby button in the bottom left-hand corner of the monitor or the shutdown button on the interface.
2. Cut the power supply by setting the main switch to **0**.

Refer to the warning in Chapter 2 concerning switching off the device.


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# 8. CLEANING, MAINTENANCE AND REPAIRS

In the event of a malfunction, only Echosens staff or local representatives are authorized to work on the FibroScan and its accessories. Any work performed by an unqualified person will terminate the guarantee.

## 8.1. CLEANING

Apply the following recommendations to clean or disinfect the device, probes, and accessories.

Failure to observe these recommendations may result in damage to the device and the probes, which will then no longer be covered by the guarantee.

### Recommendations

- Always wear eye protection and gloves to prevent injury.
- Observe the expiry dates of cleaning products and decontamination solutions.
- Ensure that the contact time and concentration of the cleaning product and decontamination solution are appropriate for the equipment used. Carefully apply the instructions given on the label of the cleaning product and the decontamination solution.
- Carefully read the recommendations from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Food and Drug Administration (FDA), if applicable in the country.

### *8.1.1. Cleaning the device (painted, metallic, glass, or plastic surfaces and screen)*

Refer to the warning in Chapter 2 concerning cleaning.

Surfaces must be cleaned in strict compliance with the following procedures:

1. clean using a soft cloth soaked in the recommended cleaning product,
2. if necessary, rinse using a soft cloth soaked in water,
3. wipe the surface using a soft cloth soaked in the recommended decontamination solution,
4. if necessary, dry carefully using a soft, clean, absorbent cloth.

### Precautions

Do not spray any cleaning or disinfectant product directly on the device. Leaks may damage the system, which would then no longer be covered by the guarantee.

Do not scratch the screen.


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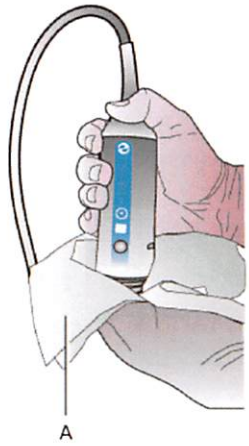
### 8.1.2. Cleaning the probe (housing, cable and transducer)

It is not necessary to switch off the device before cleaning the probe.

Surfaces must be cleaned in strict compliance with the following procedures:

1. Gently remove the gel using a soft cloth or wipe.




***Cleaning the probe: A:*** *Wipe.*

2. Remove all traces of bodily fluid by cleaning the surfaces using a soft cloth or wipe soaked in the recommended cleaning product.
3. If necessary, rinse the cleaned surfaces using a soft cloth soaked in water.
4. Dry, if necessary, using a dry cloth.
5. Wipe the surfaces using a soft cloth or wipe soaked in the recommended decontamination solution.
6. Dry, if necessary, using a soft dry cloth.
7. Examine the transducer and probe cable for any damage such as cracks, breakage, or liquid leakage.

If any damage is observed, stop using the probe and contact Echosens or its local representative: service@echosens.com

**Precautions**

Do not submerge or soak the probe.

Apply the cleaning product and decontamination solution to the soft cloth, not directly on the surface to be cleaned.

The probe must be cleaned after every use or between patients. Prior cleaning is necessary in order to ensure effective decontamination.

Do not use a surgical brush to clean the probe. Even the use of flexible brushes could damage the probe.

Take care not to introduce any cleaning product or decontamination solution into the probe connector.

### 8.1.3. Recommended cleaning products

Echosens recommends use of the following products :

- Pure water, soapy water.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- Detergent with neutral pH (5 to 8).
- Recommended decontamination solutions (see below).

Cleaning products which **must not be used** are:

- Abrasive products (such as "Cif" and scouring powders).
- Alkaline detergents (pH > 9), bleach, etc.
- Sulfuric, acetic, nitric, hydrochloric, and oxalic acid, etc.
- Soda, potash, ammonia, etc.
- Alcohols: Methanol, ethanol, etc.
- Hydrocarbons and solvents: Unleaded petrol, acetone, MED, MIBK, toluene, xylene, benzene, trichloroethylene, diluent, nail varnish solvent, etc.

### *8.1.4. Recommended decontamination solutions*

The decontamination solutions recommended below are suitable for use on the device and probes.

| Cleaning and decontamination solution | Origin | Type | Active ingredient |
|---|---|---|---|
| Certainty Disinfectant Wipes (DIN:02325853) | Canada | Wipes | Quaternary ammonium |
| Clorox Disinfectant Wipes (DIN:02319462) | Canada | Wipes | Quaternary ammonium |
| Zep Clean'ems Spirit II Disinfectant Towels (DIN:02290588) | Canada | Wipes | Quaternary ammonium |
| 105 Spray | USA | Vaporizer | Quaternary ammonium |
| Ascend | USA | Liquid | Quaternary ammonium |
| Control III | USA | Liquid | Quaternary ammonium |
| Coverage Spray | USA | Vaporizer | Quaternary ammonium |
| End-Bac II | USA | Liquid | Quaternary ammonium |
| PI-Spray | USA | Vaporizer | Quaternary ammonium |
| PI-Spray II | USA | Vaporizer | Quaternary ammonium |
| Thericide Plus | USA | Liquid | Quaternary ammonium |
| Thericide Plus | USA | Vaporizer | Quaternary ammonium |
| Clinell Wipes | United Kingdom | Wipes | Quaternary ammonium |
| Tristel Wipes System | United Kingdom | Wipes | Chlorine dioxide |
| Tuffie | United Kingdom | Wipes | Quaternary ammonium |
| Surfanios Premium | France | Liquid | Quaternary ammonium |
| Aniosurf Premium | France | Liquid | Quaternary ammonium |
| Wip'Anios | France | Wipes | Quaternary ammonium |
| Wip'Anios Premium | France | Wipes | Quaternary ammonium |
| Surfa'Safe SH | France | Vaporizer | Quaternary ammonium |
| Viraclean | France | Vaporizer | Quaternary ammonium |


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In addition to the list of recommended decontamination products, any alcohol-free decontamination product using quaternary ammonium as its active ingredient may be used to decontaminate the probes.

## 8.2. CALIBRATING THE PROBE

The probe contains mechanical parts that may shift slightly over time.

The probe must therefore be calibrated periodically. Beyond the period indicated on the calibration certificate, the manufacturer no longer guarantees the performance characteristics of the probe.

When an examination is opened, a window displays the expiry of the calibration of your probe. When this is displayed, contact Echosens or its local representative to arrange calibration: service@echosens.com

During the examination, the message "Calibrate the probe" is displayed in the message zone.

At the end of an examination, the message "Probe out of calibration" is displayed on the printed examination report.

## 8.3. TROUBLESHOOTING

| Events | Solutions |
|---|---|
| The probe is no longer calibrated. | Contact ECHOSENS or its local representative: service@echosens.com |
| The standby pushbutton is inoperative. When pressed, the device won't turn on. | Check that the device is connected to a correctly powered AC supply socket (test another electrical device on this same socket) and that the main switch is in the I position.<br>Have the main switch's fuses checked by the maintenance department. |
| The standby pushbutton is on, but the software is not booting. | Turn the device off, then on again. |

In the event of a failure or malfunction, please contact Echosens or its local representative: service@echosens.com.


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# 9. CONFIGURING THE FIBROSCAN

## 9.1. ENTERING CONFIGURATION MODE

To enter Configuration mode, press in the Home screen.

A screen then asks for an identifier and password.

The available passwords and identifiers are in ascending order of the features to which they give access (Note: case-sensitive) :

### Operator Level

User name : Operator

Password : **0 P 3 R**

### FibroScan Administrator Level

User name : FibroScan Administrator

Password : **5 U P 3 7 4 D M 1 N**

In general, click [Apply] to confirm the input and save the new data.

## 9.2. LOCALIZATION TAB

This tab is used to configure date, time and user interface language.

### Date and time

Press [Modify] and then enter the system date and time, and press [Save] to save the data.

### Language

Select the interface language and examination report from the list.

## 9.3. INSTITUTION TAB

This tab lets you input the institution contact details.

### Information concerning the institution

The information entered will be displayed on the report.


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### Logo

Press [Modify]. If an image filed called logo.bmp is present in the root of the USB device connected to the device, the logo is automatically modified. The logo appears on the examination report.

[Reset] deletes the logo from the examination report.

## 9.4. PRINTER TAB

This tab lets you configure examination report printing.

***For an Operator***

### Auto-print count

Enter a digit corresponding to the number of reports to print at the end of each examination.

The digit 0 is input by default.

***For a FibroScan Administrator***

### Printing format

A4 or Letter

The Letter format matches the American paper format.

### Printers

| | |
|---|---|
| [Update] | Update the list of printers. |
| [Add printer] | Lets you add a printer. You can add by port, by IP address or by selecting a shared printer. |
| [Set as default] | Lets you define a printer as default printer. |
| [Delete printer] | Lets you delete a printer. Follow the on-screen instructions. |
| [Search for printer patch] | Lets you add a printer patch supplied by Echosens. |
| [Stop any printing in progress] | Lets you cancel current printing operations. |

## 9.5. DATA TAB

This tab is used to import, export and archive examination files. It can only be accessed by users with FibroScan administrator rights.

A removable USB storage device must be connected.


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### Archive

Lets you copy examinations and examination reports (PDF) for the period selected onto a removable USB storage device. The files are saved in a folder named "backup". An .xls file containing the examination results for the period selected can also be exported.

### Export

Lets you enable automatic or manual export of examinations in .fibx format to a USB storage device at the end of each examination. The files are stored in the root directory of the storage device and can be anonymized..

### Import

Lets you import .fibx examination files from a removable USB storage device.

The files are stored in the root directory of the storage device.

## 9.6. USER TAB

This tab lets you define user accounts and link specific rights to them according to account type: Operator or FibroScan Administrator. The configuration of user accounts is accessible only with FibroScan Administrator level.

## 9.7. CONNECTIVITY TAB

The configuration of network connections is accessible only through the FibroScan Administrator level.

This operation must only be performed by personnel trained in network management.

IP address This can be configured statically or dynamically via the DHCP protocol. To configure the IP address manually, click [Manual] and complete the fields.

### Network

This tab is used to specify the network parameters of the device. This includes: Device name, IP address, Sub-network mask, and Gateway.

### Directory

File sharing consists of making the contents of a directory available via the network. This tab lets you define a shared directory on the network. To do so, simply specify the absolute access path of the directory (\\computer\name_of_share), as well as the associated login and password.

### DICOM

This tab is used to specify the DICOM connections of the device.

A key is required to enable the DICOM connectivity (to obtain this activation key, contact ECHOSENS or its local representative).

The hospital IT department will provide user support for the configuration of these parameters. If necessary, refer to the FibroScan Devices DICOM Conformance Statement.


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| | |
|---|---|
| [Worklist] | Lets you define the server through which the device will perform a patient search. If necessary, it is possible to filter the patient list by use (0008,0060). By default, it is filtered by AE Title. |
| [Storage] | Lets you define the servers to which the device will export the examination report. It is possible to choose the format of the report: JPEG image and/or PDF document. |

The Name, IP address/Host name, Port and AE Title must be input for each of the DICOM connections defined. These parameters are generally available from the network administrator.

The AE Title is a unique identifier of the device. Please note that it is case-sensitive.

The [Check] button lets you test the connection with the selected server.

### FibroView

This tab is used to activate the connection with the FibroView Data Solution.

The network address of the FibroView Data Solution server must be entered, starting with http://. The [Check] button lets you test the connection with the Data Solution.

To enable Wi-Fi, the wireless network name (SSID) and password must be defined. The security level of the connection is defined by choosing a protocol (WPA or WPA2, with or without pre-shared key, PSK) and completed with an encryption method (TKIP or AES).

The hospital IT department will help users to configure the Wi-Fi connection, particularly as regards choosing the correct security level.

## 9.8. EXAMINATION TAB

This tab is used to enable or disable the available software options. It can only be accessed by users with FibroScan administrator rights.

### CAP activation

Enables or disables the optional CAP display.

A key is required to enable the CAP (to obtain this activation key, contact Echosens or its local representative).

### Measurement conditions

Enables the transfer of the measurement conditions to the examination report.

## 9.9. SYSTEM TAB

### *9.9.1. Information*

This tab displays information about the system and the software: serial numbers (device, probes, etc.), software and firmware version numbers,remaining disk space and total disk space,device use time.


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### 9.9.2. Logs

***For a FibroScan Administrator***

The log file tracks system activity and gives the operator a history of the events that occurred during use of the FibroScan software. This tab lets you view and export the log files.

[Export] Exports the log file.

From any user account, save the Log file by pressing the [Export] button after connecting a back-up device (usually a USB key connected to one of the device's USB ports). The file is exported to the root directory, and its name contains:

- the device's serial number,
- the date and time the file was created.

The USB device may not be recognized immediately after insertion. In that case, press [Export] again if an error message is displayed.

### 9.9.3. Service

This tab gives access to the troubleshooting options.

***For an Operator***

[Eject CD] To eject the CD from the drive.

***For a FibroScan Administrator***

[Launch Program] To execute an ECHOSENS-certified program present on a USB storage device.

A removable USB device must be connected.

[Probe Memory] Displays the characteristics of the probes connected to the device.

[Screen Calib.] Touch screen calibration.

[Check Disk] Hard disk check.

[Clear Database] Clears the database. **Note that the examination files remain physically present on the hard disk.**

[Upgrade Device] Update of device software using a USB device supplied by Echosens.

Remote Access Enables Echosens to access your device remotely. Once launched, make a note of the TeamViewer identifier so you can pass it on to your Echosens contact person.


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### 9.9.4. General

***For an Operator***

#### Delay before application lock

The delay before disconnection is the idle period after which the application will disconnect. This period may range from 5 to 55 minutes.

***For a FibroScan Administrator***

#### Patient data security

If this security is activated, by default no patient data will be displayed in Archive and Acquisition modes. In this case, to display patient list or specific patient details, click on the [Display patients] or [Display patient details], respectively.


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# 10. SYMBOLS ON THE DEVICE

## 10.1. CONNECTORS

| | |
|---|---|
| | DVI-I output |
| | Ethernet connector RJ45 |
| | USB connector |
| | Elastography probe connection |
| | Location for the connector of the unconnected probe. |

## 10.2. WARNINGS

| | |
|---|---|
| | Holder not intended for a FibroScan probe |


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Do not cover the vents

(CAUTION: This symbol does not appear on devices manufactured before 2013).

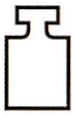
Warning: Only Echosens-approved maintenance personnel are authorized to open and modify the FibroScan device.

Refer to the user manual to ensure operator and patient safety.

(CAUTION: This symbol does not appear on devices manufactured before 2013).

Year and country of manufacture

(CAUTION: This symbol does not appear on devices manufactured before 2017).



Weight of device with accessories

(CAUTION: This symbol does not appear on devices manufactured before 2013).

Do not push or lean on the top of the FibroScan device.

To avoid tipping the FibroScan when moving it, move it slowly sideways and steer it firmly by holding the decorative rods on the front and back of the device.

To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.

(CAUTION: This symbol does not appear on devices manufactured before 2013).

## 10.3. MARKING AND ELECTRICAL SAFETY

CE
0459

CE marking and notified body identification number

Certificate affixed on July 21, 2011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**Scrapping the button cell battery**

The FibroScan uses a 'button cell' battery. This is a long-life battery and it may never need replacing.

In the event of replacement, however, do not discard the old battery with ordinary household waste. Contact your local waste processing department for the address of the nearest battery disposal location.

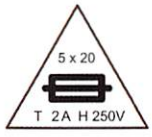
**Scrapping the FibroScan and its probe(s)**

To reduce the risk of pollution by electrical and electronic waste, and within the framework of European Directive 2011/65/EC, the FibroScan device and its probe(s) must not be discarded with ordinary household waste. Contact the local electrical and electronic waste processing service for instructions.

Equipotential terminal

Protective ground

Alternating current




2-A accessible time-delay fuses

Applied part type B

Standby pushbutton

Main switch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## 10.4. NOTE:

The following symbols appear on devices manufactured before 2013.

Do not cover the vents.

WARNING: WARNING: only Echosens-approved maintenance personnel are authorized to open and modify the FibroScan device.

2-A accessible time-delay fuses

Applied part type B

The serial number marked on the device identifies the FibroScan uniquely.


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# 11. TECHNICAL CHARACTERISTICS

## 11.1. CHARACTERISTICS OF THE DEVICE

| | |
|---|---|
| Manufacturer | Echosens<br>30 place d'Italie<br>75013 PARIS - France |
| Model | FIBROSCAN 502 TOUCH |
| MDD Classification | Class IIa according to directive 93/42/EC |
| Class of protection against electric shock | Class I |
| Type of part applied | B |
| Software security class | B |
| Class and group according to CISPR 11 | Group I Class A |
| IP code | IPX0: The device without probe is not protected against liquids. |
| Operating mode | Continuous operation<br>Charge time = $T_{charge}$ = 10 min.<br>Rest time = $T_{rest}$ = 15 min. |
| Mechanical Index | MI < 1.0 for all operation modes. |
| Thermal Index | TI < 1.0 |

### 11.1.1. Computer characteristics

| | |
|---|---|
| Operating system | Windows Embedded |
| Permanent storage system | Hard disk |

### 11.1.2. Metrological performance

Note: The quantities measured are shear wave speed written as 'Vs' and stiffness written as 'E'.

| | |
|---|---|
| Shear wave speed | Min.: 0.8 m/s<br>Max.: 5.0 m/s |

| | | Shear wave speed Vs (m/s)* | | | | | |
|---|---|---|---|---|---|---|---|
| | | S+ | | M+ | | XL+ | |
| Vs (m/s) | Phantom number | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) |
| Zone 1 | 1 | - 0.8 | 0.8 | 0.7 | 0.6 | 1.3 | 0.0 |
| | 2 | − 5.8 | 0.8 | − 4.7 | 0.8 | − 3.9 | 0.0 |


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| | | Shear wave speed Vs (m/s)* | | | | | |
|---|---|---|---|---|---|---|---|
| | | S+ | | M+ | | XL+ | |
| Vs (m/s) | Phantom number | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) |
| 1.14 | | | | | | | |
| Zone 2<br>1.79 | 1<br>2 | - 9.0<br>- 13.5 | 0.8<br>2.0 | - 11.3<br>- 11.5 | 0.9<br>0.9 | - 12.4<br>- 13.9 | 1.4<br>1.4 |
| Zone 3<br>2.77 | 1<br>2 | - 4.5<br>3.6 | 0.7<br>0.7 | - 4.3<br>- 3.1 | 0.9<br>1.9 | - 11.0<br>- 9.2 | 3.1<br>2.2 |

* Values obtained with CIRS phantoms E-1493-1 (1) and E-1493-2 (2)

** As defined by ISO 5725-1 1994

| | |
|---|---|
| Stiffness | Min.: 2.0 kPa<br>Max.: 75 kPa |

| | | Stiffness E (kPa)* | | | | | |
|---|---|---|---|---|---|---|---|
| | | S+ | | M+ | | XL+ | |
| E (kPa) | Phantom number | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) |
| Zone 1<br>3.9 | 1<br>2 | - 1.5<br>- 11.3 | 1.7<br>1.6 | 1.3<br>- 9.2 | 1.3<br>1.5 | 2.6<br>- 7.7 | 0.0<br>0.0 |
| Zone 2<br>9.6 | 1<br>2 | - 17.0<br>- 25.1 | 1.7<br>4.0 | - 21.3<br>- 21.6 | 1.7<br>1.7 | - 23.1<br>- 25.7 | 2.8<br>2.8 |
| Zone 3<br>23.3 | 1<br>2 | - 8.7<br>7.6 | 1.4<br>1.4 | - 8.3<br>- 5.9 | 1.8<br>3.8 | - 20.5<br>- 17.3 | 6.3<br>4.4 |

* Values obtained with CIRS phantoms E-1493-1 (1) and E-1493-2 (2)

** As defined by ISO 5725-1 1994

| | |
|---|---|
| CAP | Minimum: 100 dB/m<br>Maximum: 400 dB/m |

| | Controlled Attenuation Parameter CAP (dB/m)* | | | |
|---|---|---|---|---|
| | M+ | | XL+ | |
| CAP (dB/m) | Bias** (%) | Precision** (%) | Bias** (%) | Precision** (%) |
| 145 (1) | - 1.4 | 0.0 | 6.5 | 1.0 |
| 235 (2) | - 0.4 | 0.0 | - 3.4 | 0.4 |
| 340 (3) | - 4.9 | 0.1 | - 3.5 | 0.4 |

* Values obtained with Madsen phantoms $Ph^{1}150$ (1), $Ph_{1}^{250}$ (2) and Ph1350 (3)

** As defined by ISO 5725-1 1994


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### 11.1.3. Electrical characteristics

| | |
|---|---|
| Power supply | 100-240 V ~ 50–60 Hz |
| Apparent power | 70-75 V·A or 130-150 V A, depending on year of production |
| Fuse | 2 x type 5x20 T2.0AH 250V |

### 11.1.4. Mechanical characteristics

| | |
|---|---|
| Dimensions | 1350 mm x 680 mm x 610 mm (H x L x D) |
| Weight | 41 kg (with accessories) |

### 11.1.5. Environmental characteristics

| | |
|---|---|
| Operating temperature | + 10°C to + 40°C (+ 50°F to + 104°F ) |
| Operating humidity | 30% to 75% relative humidity, not condensed. |
| Maximum operating altitude | 3000 m |
| Operating atmospheric pressure | 700 hPa to 1060 hPa |
| Storage and transportation temperature | – 20°C to + 50°C (- 4°F to 122°F ) |
| Storage and transportation humidity | 10% to 85% relative humidity, not condensed. |
| Maximum altitude for storage and transportation | 5000 m |
| Storage and transportation atmospheric pressure | 540 hPa to 1060 hPa |

### 11.1.6. Additional information

| | |
|---|---|
| Power cables (according to country) - Length < 3 m | 1 x Australia power cable<br>1 x Brazil power cable<br>1 x China power cable<br>1 x Switzerland power cable<br>1 x EU power cable<br>1 x UK power cable<br>1 x US/CA Hospital Grade power cable |

## 11.2. CONSUMABLES

*Not applicable.*


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# 12. REGULATIONS

Electromagnetic interference (EMI) is a signal or emission, conveyed through open space or through electrical or signal conductors, which may severely disrupt radio navigation or other safety services, or seriously and frequently damage, obstruct or interrupt an authorized radio communication service. These communication services include, but are not limited to, commercial AM/FM radio services, television, cellular telephone services, radio detection, air traffic control, radio paging and GSM systems. These authorized services, along with unintentional sources of disturbance, such as digital equipment, including computer systems, contribute to the electromagnetic environment.

Electromagnetic compatibility is the ability of the elements of an electronic device to interact correctly with the electronic environment. Although this computer system has been designed to conform to the restrictions of the EMI regulatory body, there is no guarantee concerning interference that may occur in a specific installation. Should the device generate interference with radio communication services (this may be determined by turning the device off and on), users are encouraged to attempt to correct this phenomenon by adopting one or all of the following measures:

- Change the orientation of the reception aerial.
- Reposition the computer relative to the receiver.
- Move the computer away from the receiver.
- Connect the computer to a different power socket such that the computer and receiver are on different branch circuits.

## 12.1. ELECTROMAGNETIC EMISSIONS

The FibroScan 502 TOUCH is designed for use in the electromagnetic environment defined below. The customer or the user of the FibroScan 502 TOUCH must ensure that it is used in this type of environment.

| Emissions testing | Compliance | Electromagnetic Environment - Directives |
|---|---|---|
| CISPR RF emissions 11 | Group 1 | The FibroScan 502 TOUCH uses RF energy for its internal functions only. Consequently, its RF emissions are very low and unlikely to cause any interference with nearby electronic equipment. |
| CISPR RF emissions 11 | Class A | The FibroScan 502 TOUCH may be used on all premises other than domestic premises and those directly connected to the public low voltage energy grid used to supply domestic buildings. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker IEC 61000-3-3 | Compliant | |


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NOTE: The use of cables and/or accessories not specified in the User Manual may increase the device's emissions.

## 12.2. ELECTROMAGNETIC IMMUNITY (1)

In the following cases, electrostatic charge may be generated:

- By triboelectric effect: By rubbing two different materials together (conductive or insulating), one gains a positive charge and the other a negative charge. The further the two materials are from each other on the triboelectric series, the greater the charge is likely to be.
- By electrostatic effect: Shift of electrostatic charges due to proximity of another charge.

The FibroScan 502 TOUCH is designed for use in the electromagnetic environment defined below. The customer or the user of the FibroScan 502 TOUCH must ensure that it is used in this type of environment.

| Immunity test | IEC 60601 test level | Compliance | Electromagnetic Environment - Recommendations |
|---|---|---|---|
| Electrostatic Discharge IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV on contact<br>± 8 kV through air | Floors should be wooden, concrete or ceramic. If the floor is covered with a synthetic material, the relative humidity must be at least 30%. %. |
| Spike/Burst IEC 61000-4-4 | ± 2 kV Power supply<br>± 1 kV Input/Output | ± 2 kV Power supply<br>± 1 kV Input/Output | The quality of the electrical network must be that of a typical commercial or hospital environment. |
| Voltage shocks IEC 61000-4-5 | Differential mode<br>± 1 kV<br>Common mode<br>± 2 kV | Differential mode<br>± 1 kV<br>Common mode<br>± 2 kV | The quality of the main supply must be that of a typical commercial or hospital environment. |
| Voltage drops, short interruptions and supply inlet voltage variation IEC 61000-4-11 | < 5 % $U_T$ [1] for 10 ms.<br>40 % $U_T$, for 100 ms.<br>70 % $U_T$, for 500 ms.<br>< 5 % $U_T$, for 5 s. | < 5 % $U_T$, for 10 ms.<br>40 % $U_T$, for 100 ms.<br>70% $U_T$, for 500 ms.<br>< 5 % $U_T$, for 5 s. | The quality of the electrical network must be that of a typical commercial or hospital environment. If the user of the FibroScan device 502 TOUCH requires uninterrupted operation during electrical power cuts, it is recommended that the FibroScan device 502 TOUCH be powered by an uninterruptible power supply or battery. |
| Magnetic field immunity at supply frequency (50-60 Hz) IEC 61000-4-8 | 3 A/m | 3 A/m | Supply frequency magnetic fields must be those of a typical commercial or hospital environment. |

1. $U_T$ : network power supply voltage measured before the test


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## 12.3. ELECTROMAGNETIC IMMUNITY (2)

The FibroScan 502 TOUCH is designed for use in the electromagnetic environment defined below. The customer or the user of the FibroScan 502 TOUCH must ensure that it is used in this type of environment.

| Immunity test | IEC 60601 test level | Compliance | Electromagnetic Environment - Directives |
|---|---|---|---|
| | | | Portable and cellular RF communication equipment must be kept far away from the FibroScan device 502 TOUCH (including its cables), at a distance greater than the recommended distance calculated using the equation applicable to the emitter frequency. |
| | | | **Recommended separation distance** |
| Conducted RF IEC 61000-4-6 | 3 $V_{rms}$ 150 kHz to 80 MHz | 3 $V_{rms}$ | $d = 1.17 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz |
| | | | $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz |
| | | | where P is the maximum emitter power in watts (W), as specified by the emitter manufacturer, and d is the recommended separation distance in meters (m). The strength of EM fields for fixed emitters, as determined by a study. [2] The electromagnetic range of the site must be within the compliance level required in each frequency band. [3] Interference may occur in the vicinity of devices bearing the following symbol: |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band is applicable.

NOTE 2: These recommendations may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection caused by structures, objects and individuals.

NOTE 3: The use of cables and/or accessories not specified in the User Manual may reduce the device's immunity.

2. The strength of EM fields for fixed emitters such as commercial AM/FM radio broadcasting services, television, cellular telephone services, radio detection, air traffic control, radio paging receivers and GSM services cannot be accurately predicted. To assess the EM environment caused by fixed emitters, a site EM study must be conducted. If the field strength measured at the location where the FibroScan device 502 TOUCH is used exceeds the compliance levels mentioned above, correct operation of the FibroScan device 502 TOUCH must be checked. If abnormal performance is observed, additional measurements may be required after, for example reorienting or moving the FibroScan 502 TOUCH.

3. In the frequency range 150 kHz – 80 MHz, field strengths should ideally be lower than 3 V/m.


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NOTE 4: In case of any disturbance in the electromagnetic environment of the FibroScan 502 TOUCHa message is displayed (see the Message Area chapter) and no measurements can be carried out.

## 12.4. RECOMMENDED SEPARATION DISTANCES

(Between portable or cellular RF communication devices and the FibroScan 502 TOUCH)

The FibroScan 502 TOUCH is designed for use in an electromagnetic environment in which RF disturbance is controlled. The customer or the user of the FibroScan 502 TOUCH can take precautions against interference by maintaining a minimal distance between the portable or cellular RF communication equipment (transmitters) and the FibroScan 502 TOUCH as recommended below according to the maximum power of the communicative device.

| **Maximum transmitter output power (W)** | **Separation distance according to transmitter frequency (m)** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** $d = 3.5/3\sqrt{P}$ | **80 MHz to 800 MHz** $d = 3.5/3\sqrt{P}$ | **800 MHz to 2.5 GHz** $d = 7/3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.69 | 3.69 | 7.38 |
| 100 | 11.67 | 11.67 | 23.33 |

For emitters whose maximum power is not listed above, the recommended separation distance in meters (m) can be estimated using the applicable equation at the transmitter's frequency, where P is the maximum transmitter power in watts (W) as specified by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range is applicable.

NOTE 2: These recommendations may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection caused by structures, objects and individuals.


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